U.S. Department of Justice

Civil Division
Commercial Litigation Branch
Fraud Section

JAY:NAW:FEBoujaoude
46-57-1501

F. Elias Boujaoude
Telephone: (202) 307-0804
E-Mail: F.E.Boujaoude@usdoj.gov

175 N Street, N.E.
Room 9.212
Washington, DC 20002
[Overnight Address]

P.O. Box 261
Ben Franklin Station
Washington, D.C. 20044
[Regular Mail Address]

June 15, 2023

VIA ELECTRONIC MAIL

Special Master Cohen
Carl B. Stokes U.S. Courthouse
801 West Superior Avenue
Cleveland, OH 44113-1837
David@SpecialMaster.Law

Re: *In re National Prescription Opiate Litigation*, No. 17-md-2804: Dispute Regarding DEA's Production of ARCOS Transactional Data for 2015 to 2019

Dear Special Master Cohen:

The Department of Justice, on behalf of the Drug Enforcement Administration ("DEA"), respectfully submits this letter in opposition to the Plaintiffs' Executive Committee's ("the PEC") June 8, 2023 motion to enforce a subpoena ("the Subpoena") to DEA for production of certain Automation of Reports and Consolidated Orders Systems ("ARCOS") data. Specifically, the PEC seeks complete transactional data for all prescription buprenorphine, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, opium powdered, oxycodone, oxymorphone, and tapentadol transactions in all states and territories in the United States for the period of January 1, 2015 through December 31, 2019.

For the reasons set forth below, the Subpoena disregards the balanced approach to the disclosure of ARCOS data set forth by this Court's prior orders, imposes an undue burden on DEA that is disproportionate to the needs of the case at this juncture, and fails to provide a reasonable time to comply. Accordingly, the Court should deny the PEC's motion.

RELEVANT PROCEDURAL HISTORY

The dispute over ARCOS data predates the MDL. Plaintiffs first sought access to the ARCOS database via a *Touhy* request in early October 2017 for use in *City of Cincinnati v. AmerisourceBergen Drug Corp.*, an early opioid case out of the U.S. District Court for the

Southern District of Ohio. *See* Order re: ARCOS/DADS Database at 1, ECF No. 112 (setting forth history of the ARCOS dispute).[1] DEA denied that request in light of an order staying discovery pending a decision of the Judicial Panel on Multidistrict Litigation whether to create an MDL. *Id.* at 2. Chief Judge Sargus, who was presiding over that case and eighteen other related opioid cases, entered an order authorizing the City of Cincinnati to serve a subpoena for ARCOS data to tee up the dispute for the judge who would ultimately preside over the MDL. *Id.* at 1.

On February 2, 2018, after creation of the MDL, Judge Polster directed the MDL Plaintiffs and DEA to meet and confer regarding an ARCOS production noting both "the legitimate need for Plaintiffs to obtain this data" and the need to tailor the production "in a way to address the DEA's concerns." *Id.* at 2. Because the parties could not agree to parameters for the production, the Court held a hearing on February 26, 2018. At that hearing, Judge Polster repeatedly emphasized the need for a balanced approach to the production of ARCOS data. *See* Tr. at 15, ECF No. 156.

On April 11, 2018, the Court ordered DEA to produce complete transactional data on four drugs across six states from 2006 through 2014. Order Re ARCOS Data at 1, ECF No. 233. One month later, the Court expanded the directive to include transactional ARCOS data for the same four drugs across all fifty states. Second Order Re ARCOS Data at 2, ECF No. 397. And after yet another request, the Court ordered DEA to produce transactional ARCOS data for an additional ten drugs. Third Order re ARCOS Data at 2, ECF No. 668.

As the Court is aware, ARCOS data was initially produced pursuant to a protective order. *See generally* Protective Order, ECF No. 167. On June 13, 2018, several media companies intervened in the case seeking access to the data. *See* Briefing Order re Public Record Requests at 2 n.1, ECF No. 611; Br. in Support of Disclosure of ARCOS Data, ECF No. 718. Ultimately, this Court denied their request. *In re Nat'l Prescription Opiate Litig.*, 325 F. Supp. 3d 833 (N.D. Ohio 2018). The companies appealed to the Sixth Circuit, which vacated the protective order. *In re Nat'l Prescription Opiate Litig.*, 927 F.3d 919 (6th Cir. 2019). DEA's objections to production below are separate and distinct from the questions addressed in the Sixth Circuit's decision.

ARGUMENT

I. The Subpoena Contravenes the Balanced Approach Set by the Court's June 26, 2018 Order

In response to the PEC's prior requests for ARCOS data, Judge Polster has carefully balanced the needs of the Plaintiffs for this data against the government's law enforcement and resource concerns. Consistent with this balanced approach, when Judge Polster ordered DEA to produce the final tranche of ARCOS data in June 2018, he stated that "[t]his directive for release of additional ARCOS data will be the last one made by the MDL court." Third Order Re ARCOS Data at 2, ECF No. 668 (emphasis supplied). That instruction was made after three

[1] All ECF citations refer to the MDL docket.

separate requests by the PEC for more data. Thus, notwithstanding the Court's recognition that the data had been "very helpful," *id.* at 1, it also reasonably concluded that the PEC's access to ARCOS data should not be unlimited. And while this Court's imposition of a protective order governing ARCOS data was overturned by the Sixth Circuit, nothing in the Court of Appeals' decision disturbs the prior balance appropriately struck by Judge Polster regarding the further production of ARCOS data, which is binding on the Special Master. *See La Buy v. Howes Leather Co.*, 352 U.S. 249, 256 (1957) ("The use of masters is to aid judges in the performance of specific judicial duties . . . not to displace the court.").

II. The Subpoena Imposes an Undue Burden on DEA that is Disproportionate to the Needs of the Case

A party issuing a subpoena "must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena." Fed. R. Civ. P. 45(d)(1). Furthermore, a person seeking discovery is limited to "any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case." Fed. R. Civ. P. 26(b)(1). Parties seeking the production or inspection of documents within the scope of discovery "must describe with reasonable particularity each item or category of items to be inspected." Fed. R. Civ. P. 34(b)(1)(A).

Contrary to the PEC's contention, DEA *does* dispute the relevance—and utility—of more recent ARCOS data to the remaining claims in the case, as it indicated in its objection letter. *Compare* PEC Letter Mot. at 2 ("DEA also appears not to dispute the relevancy of ARCOS data for the more recent 2015 to 2019 period."), *with* Ex. A, DEA Objection Letter at 2 ("More fundamentally, it is unclear how the requested information is relevant to Plaintiffs' claims or proportional to the needs of the case at this juncture."). [2] And notwithstanding that this Court and the Sixth Circuit found the previous tranche of data relevant, the PEC has a continuing obligation to establish why *this* set of evidence is relevant.

It is unclear how updated ARCOS data would be probative of the remaining claims in the MDL. In this regard, the PEC argues that "2015 to 2019 transactional ARCOS data is as relevant to the cases against these Defendants being litigated in 2023 as the earlier-period data was relevant . . . to cases against other Defendants that were being litigated five years ago in 2018." PEC Letter Mot. at 2. The PEC also asserts that the data is "important for settlement

---

[2] The PEC also erroneously states that based on discussions with counsel, "DEA is amenable to producing ARCOS data for *some but not all* of the opioids for which it previously produced ARCOS data in 2018." *See* PEC Letter Mot. at 1. While discussions between the PEC and DEA regarding the Subpoena were cooperative and conducted in good faith, the PEC misstates the government's position. Counsel for the government never indicated that DEA was amenable to the production of additional ARCOS data—counsel indicated that DEA was amendable *to receive* any proposal to narrow the scope of the Subpoena but reserved the agency's right to stand on its initial objections. After carefully considering at least two proposals from the PEC, which failed to meaningfully alleviate the burden of production, the agency was unable to agree to those proposals and reasserted its objections.

purposes with regard to the remaining Defendants, as it provides both Defendants and the PEC with a more current view of their relative market shares." *Id.* However, the PEC has repeatedly established liability and market share with the ARCOS data in its possession. And the PEC has not demonstrated how additional ARCOS data would meaningfully alter that prior analysis.

Even were the Court to find 2015–2019 ARCOS data relevant, the burden of production must be proportional to the needs of the case. *See* Fed. R. Civ. P. 26(b)(1). The PEC has already received nine years of ARCOS data, which was sufficient for Plaintiffs to successfully litigate numerous cases in federal and state courts, and to secure tens of billions of dollars in settlements against national opioid manufacturers, distributors, and retail pharmacies. Additional ARCOS data will not enhance the PEC's litigating posture or leverage in settlement negotiations.

Providing the data requested will divert significant resources from DEA—particularly the Reports Analysis Unit ("DOIR"), the group tasked with managing the ARCOS database—at the expense of other mission-critical tasks, which include:

- producing ARCOS data to investigators in federal, state, and local government agencies throughout the country as requested to identify and combat the diversion of controlled substances into illicit channels of distributions;

- analyzing ARCOS data to provide field diversion investigators with tips, leads, and pointers of potential diversion of pharmaceutical controlled substances, including, for example, the identification of an unusually large influx of drugs into a particular county or state, which could point to illicit drug activity;

- providing data for use in active criminal, civil, and administrative cases;

- preparing regular scheduled productions of ARCOS data to law enforcement partners such as fourteen separate bi-annual reports for all state Attorneys General for their use in state law enforcement efforts; and

- validating ARCOS data for approximately 750 annual scheduled investigations—and for any resulting accountability audits—performed by DEA field offices across the country.

Ex. B, Howard Decl. ¶¶ 14–19. This is not a scenario where DEA can redistribute resources to solve the problem. As June Howard, the Unit Chief of DOIR, explains in the attached declaration "only DOIR can prepare and produce ARCOS data for litigation such as that at issue here." *Id.* ¶ 7.

The process for compiling and producing transactional ARCOS data is not automated. First, in phase one, data must be extracted from the ARCOS database and converted to excel. *Id.* ¶ 8. It must then be validated. *Id.* ¶ 9. To do so, DEA employees run an algorithm which performs forty-four different checks on the data to detect inconsistencies, missing data, etc. Though phase one is time-consuming, it is largely automated data processing. The lion's share of the work occurs during the second phase. In phase two, DEA employees must review any

flagged instances and correct them. *Id.* For example, the system might pick up an uncharacteristic surge of deliveries requiring DEA employees to determine whether this is a clerical error. *Id.* Once all the substantive checks have been performed, the data must then be downloaded to a shareable excel file. *Id.* ¶ 11.

The PEC assumes that newer data and advances in technology will expedite this process but provides no facts to support this assertion. It also ignores that the most burdensome process is validation, which requires DEA employees to cross reference any anomalies identified among millions of transactions. Validation cannot be automated, nor should it be if the parties wish to receive accurate and reliable data.

In DEA's experience, such anomalies are likely to be numerous. Most of the data requested by the PEC will have been submitted by registrants who use the Electronic Data Interchange, or "EDI" system. *Id.* ¶ 10. EDI allows registrants to import their sales and inventory data into the ARCOS database in lieu of manually uploading this information to the ARCOS portal. *Id.* This results in a dataset with many disparities depending on how a registrant organizes its data. Data submitted manually through the ARCOS portal is subject to a soft validation before it is submitted to catch minor issues such as errors in a registrant's DEA number, etc. The EDI process does *not* have this soft validation step built in. *Id.*

Ms. Howard's unit has only sixteen employees and to produce all the data requested in a month's time will require the full-time effort of five. *Id.* ¶¶ 22, 24. Diverting these employees to provide the PEC the requested data on a truncated timeline will prevent or delay DOIR from completing the vital tasks described above. *Id.* ¶ 24.

In evaluating the burden imposed on DEA, this Court should also consider the broader impact opioid-related litigation has and continues to have on DEA. The agency is facing a substantial number of requests from other parties in the MDL, in multiple other state court proceedings, and by parties seeking documents from High Intensity Drug Trafficking Area programs. Each request for documents or testimony diverts significant agency resources from their core functions. The cumulative burden imposed on DEA by all of these requests—especially given the likelihood that DEA will continue to receive similar requests (in the MDL, remanded cases, or elsewhere)—is considerable.

III. The Deadline for Compliance is Unreasonable

A court "must quash or modify a subpoena that[] fails to allow a reasonable time to comply[or] subjects a person to undue burden." Fed. R. Civ. P. 45(d)(3)(A)(i), (iv). The PEC's subpoena does just that. Plaintiffs have given DEA a month to collect, review, and produce data for millions of transactions across the country. Moreover, the data they request within two weeks—complete transactional data for oxycodone, hydrocodone, hydromorphone, and fentanyl—represents the vast majority of the data which would be produced. To comply with the first deadline alone would require the full-time effort of every member of DOIR "with no other tasks being worked on." Howard Decl. ¶ 23. The next stage of production would include drugs like morphine, which accounts for a particularly large share of the requested data and thereby compounds the burden. This deadline for compliance is demonstrably unreasonable.

The review process described above could not be completed for all the data requested within the timeline demanded by the PEC unless DEA devotes the full-time effort of at least five diversion employees (out of an office of sixteen) at the expense of all other required tasks. *Id.* ¶ 24. This is unreasonable for any non-party, let alone a federal agency serving a vital public function.

And the PEC has failed to justify the production deadlines it has imposed. It has provided no clear explanation as to why it needs additional ARCOS data so expeditiously at the significant expense of DEA resources, particularly since the active bellwethers in this case have been stayed since December.

To the extent the PEC needs updated data to identify the next class of bellwethers, it also knew that this selection was on the horizon, particularly since progress in Tracks 7–11 has been stayed. The government acknowledges that the PEC is involved in all stages of the MDL litigation, much of which occurs off the MDL docket (including related proceedings in state court). But the PEC remains responsible for ensuring that it serves subpoenas with sufficient time for non-parties to object to or comply with discovery demands.

* * *

Given the Court's prior efforts to craft an appropriate balance in requiring the production of ARCOS data, Plaintiffs have failed to demonstrate why additional data is needed—let alone, expeditiously—this far into a "mature litigation" to resolve the remaining claims. *See* Order Denying Transfer and Vacating Conditional Transfer Order, *In re Nat'l Prescription Opiate Litig.*, No. 3:21-cv-246, at *1 (J.P.M.L. Apr. 8, 2022) (finding that the MDL "has reached the point where the benefits are outweighed by the effects" of adding new cases). Given that it appears that the primary purpose of the data is to put finishing touches on settlement discussions that are already informed by the previously produced ARCOS data and volumes of other discovery in the MDL, its absence does not hamper either side's ability to put on a case or to reach a just settlement.

Unlike the PEC, DEA is not a party to this litigation despite that it has been heavily involved since the MDL's inception. The Federal Rules of Civil Procedure protect non-parties from undue burden or expense. *See* Fed. R. Civ. P. 45(d). For the reasons articulated above, the Court should deny the PEC's motion to enforce its unreasonable and unduly burdensome subpoena.

Respectfully submitted,

MICHAEL D. GRANSTON
Deputy Assistant Attorney General

JAMIE A. YAVELBERG
NATALIE A. WAITES

ALLISON C. CARROLL
JONATHAN K. HOERNER
KELLY E. PHIPPS
DAVID M. SOBOTKIN

By: */s/ F. Elias Boujaoude*

F. ELIAS BOUJAOUDE
United States Department of Justice
Civil Division, Fraud Section
175 N Street, N.E., Room 9.212
Washington, D.C. 20002
(202) 307-0804
F.E.Boujaoude@usdoj.gov

Attorneys for the U.S. Department of Justice

Cc: Renee Bacchus, Senior Trial Counsel (N.D. Ohio)
James Bennett, Assistant United States Attorney (N.D. Ohio)
Linda Singer, Motley Rice LLP
MDL2804@motleyrice.com
tracks6to10defendants@bbhps.com

Exhibit A

DEA Objection Letter

U.S. Department of Justice

Civil Division
Commercial Litigation Branch
Fraud Section

JAY:NAW:FEBoujaoude
46-57-1501

F. Elias Boujaoude
Telephone: (202) 307-0804
E-Mail: F.E.Boujaoude@usdoj.gov

175 N Street, N.E.
Room 9.212
Washington, DC 20002
[Overnight Address]

P.O. Box 261
Ben Franklin Station
Washington, D.C. 20044
[Regular Mail Address]

May 25, 2023

VIA E-MAIL

Linda Singer, Esq.
Motley Rice LLC
lsinger@motleyrice.com

Re: Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action Issued to the Drug Enforcement Administration (May 11, 2023), *In re National Prescription Opiate Litigation*, No. 1:17-md-02804-DAP (N.D. Ohio)

Dear Ms. Singer:

We write in response to the Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action Issued to the Drug Enforcement Administration ("DEA") on May 11, 2023 ("the Subpoena") issued by Plaintiffs in the above-referenced action pursuant to Federal Rule of Civil Procedure 45. A copy of the Subpoena was sent via email and Federal Express to the United States Attorney's Office in the Northern District of Ohio and was transmitted to the U.S. Department of Justice ("DOJ"), Civil Division, Commercial Litigation Branch, Fraud Section. We accepted service of the Subpoena on behalf of DEA on May 11, 2023.

First, we note that the Plaintiffs' Executive Committee submitted a letter purporting to comply with DOJ's *Touhy* regulations, 28 C.F.R. § 16.21 *et seq*., on May 11, 2023, in connection with the Subpoena ("Plaintiffs' *Touhy* letter"). DEA and DOJ are working to process this *Touhy* letter and will respond to it under separate cover in the near future. DEA and DOJ have made no determination as to whether Plaintiffs' *Touhy* letter satisfies the requirements of 28 C.F.R. § 16.21 *et seq.* Accordingly, this letter is neither an authorization nor a denial under the *Touhy* regulations, and Plaintiffs shall not infer any authorization in connection with their *Touhy* letter. DEA and DOJ specifically reserve all rights in connection with Plaintiffs' *Touhy* letter.

We further advise you that DEA and DOJ object to the Subpoena. You seek the production of complete transactional Automated Records and Consolidated Orders System ("ARCOS") data for all prescription buprenorphine, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, opium powdered, oxycodone, oxymorphone, and tapentadol transactions in all states and territories in the United States for the period of January 1, 2015 through December 31, 2019.

First, the Subpoena "fails to allow a reasonable time to comply" and subjects DEA and DOJ to "undue burden." *See* Fed. R. Civ. P. 45(d)(3)(A)(i), (iv). Plaintiffs have given DEA and DOJ three weeks to collect, review, and produce data for millions of transactions across the country. This time limit for compliance is demonstrably unreasonable, particularly given Plaintiffs' failure to adequately instruct DEA and DOJ how they expect to receive this massive amount of data. Even were it possible to provide the data within three weeks, doing so would require an extensive effort by DEA employees at the expense of their critical law enforcement mission.

More fundamentally, it is unclear how the requested information is relevant to Plaintiffs' claims or proportional to the needs of the case at this juncture. *See* Fed. R. Civ. P. 26(b)(1). Plaintiffs have already received nine years of ARCOS data, which was sufficient for Plaintiffs to successfully litigate numerous cases in federal and state courts, and to secure tens of billions of dollars in settlements against national opioid manufacturers, distributors, and retail pharmacies. When the Court ordered DEA to produce the final tranche of ARCOS data in June 2018, it unequivocally stated that, "[t]his directive for release of additional ARCOS data *will be the last one* made by the MDL court." Third Order Re ARCOS Data, *In re Nat'l Prescription Opiate Litig.*, No. 1:17-md-02804-DAP, at *2 (N.D. Ohio June 26, 2018) (emphasis supplied). Given an ever-dwindling list of lingering Defendants and a court order declaring that no further ARCOS data need be produced, Plaintiffs have failed to demonstrate why additional data is needed—let alone, expeditiously—this far into a "mature litigation" to resolve the remaining claims. *See* Order Denying Transfer and Vacating Conditional Transfer Order, *In re Nat'l Prescription Opiate Litig.*, No. 3:21-cv-246, at *2 (J.P.M.L. Apr. 8, 2022) (finding that the MDL "has reached the point where the benefits are outweighed by the effects" of adding new cases).

DEA and DOJ also object to this request to the extent that the data sought may be barred from disclosure pursuant to the law enforcement and investigative privileges, among others. The disclosure of 2018 and 2019 data, in particular, may undermine DEA's ongoing diversion efforts.

Subject to and without waiving these objections, DEA is actively assessing how it would collect the requested data, how it could produce the data, and how long it would take to do so.

*****

Unlike the Plaintiffs, the United States is not a party to this lawsuit. The Federal Rules of Civil Procedure protect non-parties from undue burden or expense. *See* Fed. R. Civ. P. 45(d). Responding to the Subpoena as drafted would result in just such a burden and expense.

DEA and DOJ may raise further objections to the Subpoena as appropriate. We invite the Plaintiffs to continue engaging with us to resolve these objections, narrow their requests, and reduce the burden on the Department which may allow DEA to consider Plaintiffs' *Touhy* request in a more favorable light and allow the Plaintiffs to obtain what they consider probative evidence in this case.

Sincerely,

/s/ F. Elias Boujaoude
F. Elias Boujaoude
Trial Attorney
U.S. Department of Justice, Civil Division
Commercial Litigation Branch, Fraud Section

Cc: Natalie Waites, Assistant Director, Commercial Litigation Branch
Renee Bacchus, Senior Trial Counsel (N.D. Ohio)
James Bennett, Assistant United States Attorney (N.D. Ohio)
Allison Carroll, Trial Attorney, Commercial Litigation Branch
David Sobotkin, Trial Attorney, Commercial Litigation Branch
Kelly Phipps, Trial Attorney, Commercial Litigation Branch

Exhibit B

June Howard Declaration

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	**MDL No. 2804**
THIS DOCUMENT RELATES TO:	
ALL CASES	**Case No. 17-MD-2804** **Judge Dan Aaron Polster**

DECLARATION OF JUNE HOWARD IN SUPPORT OF THE UNITED STATES OF AMERICA'S BRIEF POSING OBJECTIONS TO DISCLOSURE OF ARCOS DATA

I, June Howard, hereby make this declaration pursuant to 28 U.S.C. § 1764. I declare as follows:

1. I make the factual statements herein based on my personal knowledge and on information provided to me during my employment by the United States Department of Justice (DOJ), Drug Enforcement Administration (DEA), and my personal consideration of information provided by my staff. If called as a witness, I could and would competently testify to the factual statements herein.

2. I am currently the Unit Chief of the Reports Analysis Unit (DOIR), within the Targeting & Special Projects Section (DOI), Diversion Control Division (Diversion) at DEA. I have been employed by DEA since 1982 and have held the position of Unit Chief since 2018.

3. Diversion's mission is to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources to illicit ones while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs. As part of this mission, Diversion coordinates investigations within DEA and with our law enforcement counterparts at the federal and state level.

4. Diversion maintains the Automation of Reports & Consolidated Orders System ("ARCOS"), an automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level – hospitals, retail, pharmacies, practitioners, mid-level practitioners, and teaching institutions. 21 C.F.R. § 1304.33 and 21 U.S.C. 827 (d) impose a legal duty on all 822(b) Registrants, companies authorized under 21 U.S.C. § 822(b) by DEA to manufacture or distribute controlled drugs, to report all inventories, acquisitions, and dispositions of all Schedule I and II controlled substances, and of Schedule III narcotics, and the Schedule III non-narcotics GHB to ARCOS.

5. The data contained in ARCOS includes supplier name, registration number, address and business activity; buyer name, registration number and address; as well as drug code, transaction date, total dosage units, and total grams.

6. The production of the ARCOS data would be extremely burdensome to the DEA. As described below, the production of ARCOS data is particularly time-consuming. The process would be a substantial burden on my unit when considering the other productions my team members and I must regularly provide both to law enforcement and the public.

7. My unit, DOIR, is the program manager for ARCOS data. We process, analyze, review, and validate data for all productions both internally and with outside law enforcement partners. Most importantly, only DOIR can prepare and produce ARCOS data for litigation such as that at issue here.

8. The process for compiling, producing, and validating transactional ARCOS data is far from automated. First, data must be extracted from the ARCOS database and converted to excel.

9. Next, the information must then be validated. This step takes a significant amount of time. Information is validated first through an automated quality control process. This first step consists of approximately 44 edit checks which are performed on each data submission. The second step in the validation process is a second layer of quality control performed by an individual DEA analyst. During this step, an analyst performs quality control checks on the data to resolve any anomalies, identify patterns outside a registrant's standard purchases, or other irregularities. For instance, the system might pick up an uncharacteristic surge of deliveries in an entry requiring DEA employees to determine whether this is a clerical error. Within ARCOS, there are approximately 13 separate fields of data, which contain up to 80 characters each. Each of these fields must be individually validated for accuracy.

10. Registrants may submit their data either manually via a web-based interface, *i.e.*, ARCOS Online, or via Electronic Data Interchange (EDI). EDI allows registrants to import their sales and inventory data into the ARCOS database in lieu of manually uploading this information to the ARCOS Online portal. This often results in a dataset with many disparities depending on how a registrant organizes its data. Data submitted manually through the ARCOS Online portal is subject to a soft validation before it is submitted to catch minor issues such as errors in a registrant's DEA number, invalid drug codes, and the like. The EDI process does not have this soft validation step included. Most of the data requested by the PEC will have been submitted via EDI, meaning that the validation performed by hand will require extensive review before production.

11. Once all the substantive checks have been performed, the data must then be downloaded to a shareable excel file. Therefore, the validation process requires a substantial amount of time to perform.

12. The validation process is especially time-consuming for the particular opioids requested for production, namely hydrocodone and oxycodone.

13. DOIR has sole responsible for collecting, validating, and preparing such data for use in the field, at headquarters, and for law enforcement partners.

14. DOIR furnishes validated ARCOS data for approximately 750 annual scheduled investigations performed at DEA field offices across the country. We review and verify specific registrant activities and registrant self-reporting accuracy to assist diversion investigators with accountability audits. This requires our analysts to pull, validate, and process hundreds, if not thousands, of transactions per scheduled investigation.

15. DOIR also performs the analysis on ARCOS data to provide field diversion investigators with tips, leads, and pointers suggesting potential diversion of pharmaceutical controlled substances. For example, although not always an indicator of diversion, shipment of an unusually large number of drugs in a particular county or state could point to illicit drug activity. After looking at the data to rule out a legitimate need for the shipment, DEA could determine that a large shipment warrants investigation. My unit must monitor and analyze the data submitted by the over 1,300 registered drug manufacturers and distributors nationwide.

16. DOIR also analyzes and processes ARCOS data during investigations, including identifying trends and patterns, in determining whether to bring an enforcement action against a registrant. During an investigation, DOIR may receive requests for data processing and analysis from both DEA agents and investigators as well as Department of Justice attorneys.

17. My unit also provides data for use in civil, criminal, and administrative trials.

18. In addition, we produce ARCOS data to investigators in other federal, state, and local government agencies throughout the United States on a case by case basis to identify and combat the diversion of controlled substances into illicit channels of distribution.

19. DOIR also makes regularly scheduled productions of ARCOS data to law enforcement partners. For example, we furnish bi-annual reports for all state Attorneys General for their use in state law enforcement efforts. My team performs the analysis on ARCOS data every 6 months and prepares 14 separate reports that are shared with each state office.

20. ARCOS data also is utilized to support the compliance efforts of manufacturers and distributors. The 2018 Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act mandates that DEA provide drug manufacturers and distributors with access to anonymized information through ARCOS to help drug manufacturers and distributors identify, report, and stop suspicious orders of opioids and reduce diversion rates. My unit has sole responsibility for maintaining this online database. The database allows DEA-registered manufacturers and distributors to view and download the number of distributors and the amount of controlled substance (anonymized data in both grams and dosage units) each distributor sold to a prospective customer in the last six months. Not only is this data relied on by registrants in their efforts to comply with federal regulations pertaining to controlled substances, we are statutorily required to regularly provide to DEA-registered manufacturers and distributors this data.

21. To produce the requested ARCOS data, my team would need to validate millions of records. This validation would be in addition to the regular work my team must complete as described above.

22. My unit is already understaffed by roughly 30%. We currently have 6 open vacancies that are unfilled out of a total of 22 available positions.

23. In my estimate, the production of oxycodone and hydrocodone alone could not be accomplished without utilizing my entire team for a full two weeks; with no other tasks being worked on.

24. In my estimate, the full production of ARCOS data would require at least 5 of my team members to devote at least 30 days full-time to the production effort. Such production would prevent my team members from analyzing, validating, and preparing ARCOS data for the efforts described above during that period.

I declare under penalty of perjury that the foregoing is true and correct to the best of my information and belief.

JUNE HOWARD Digitally signed by JUNE HOWARD Date: 2023.06.15 11:09:34 -04'00'

Date

June Howard
Unit Chief
Reports Analysis Unit
Targeting & Special Projects Section
Diversion Control Division
Drug Enforcement Administration